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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,367	09/11/2003	Fei Chen	60589.000014	3017

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/659,367

Applicant(s)

CHEN ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-70 is/are pending in the application.
- 4a) Of the above claim(s) 34-67, 69 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22-33 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/11/07, 12/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed September 11, 2006 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is vague and indefinite because it is unclear how the fourth and fifth zones are overlapping if a calibration zone is placed between the fourth and fifth zone. Claim 5 recites that the fifth zone is a zone into which a sample not detained during migration may be adsorbed. Therefore, the fifth zone cannot be the calibration zone which would capture non-immobilized molecule. Please clarify.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 5, 9-13, 20, 22-25, 28, 30-33 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al (US 6,194,224) in view of Wei et al (US 2003/0119203) or Robinson et al (US 5,726,064).

Good et al disclose a device comprising a sample receiving zone (zone 1)(see Figures 1-3). Good et al disclose the device comprises a reagent zone (second zone) which contains labeled antibodies (non-immobilized molecule) which are specific for the analyte of interest. Good et al disclose the device comprises an area (third zone) that is overlapped by the reagent zone and extends to a test zone. Good et al disclose that

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this area (third zone) is comprised of a nitrocellulose having a pore size of 200 nm to about 500 nm (col 4). Good et al disclose the device comprises a test zone (fourth zone) having immobilized analyte (col 3 & col 4). Good et al disclose that the first zone and second zone are overlapping. Good et al disclose that the second zone and third zone are overlapping. Good et al disclose that the different zone can be comprised of different materials. Good et al disclose that the device comprises a liquid sink zone or waste pad (fifth zone) that absorbs excess liquid in the sample. Good et al disclose that the membrane can comprise latex (col 5-6). Good et al disclose that the sample receiving zone comprises a surfactant (ancillary compound) which provides better flow characteristics of the specimen (col 3 and abstract). Good et al disclose that the surfactant works especially well when the sample is a viscous sample.

Good et al differs from the instant invention in failing to teach a calibration zone comprising an immobilized binding agent having an affinity for the labeled non-immobilised molecule.

Wei et al discloses calibration zone in which a binding agent is immobilized and has affinity for a labeled conjugate (for example para. 0012). Wei et al discloses that the device can be a lateral flow device and that the calibration zones can be useful with essentially any membrane based device (page 5). Wei et al discloses that the calibration zone can be used in comparison with the detection zone to calculate the amount of analyte (p. 3, para. 39). Wei et al discloses that the use of calibration zones provides for improving sensitivity, and reducing errors that otherwise may be introduced

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by comparing data produced in one assay with data or reference data produced in a different assay (abstract & p. 1).

Robinson et al disclose a device such as a test strip (col 8) having a calibration zone located thereon. Robinson et al disclose that the calibration zone can be located downstream of a measurement zone (see col 33-34, col 9-10). Robinson et al disclose that in competitive assays the calibration zone can have an immobilized reagent which binds to labeled analogue. Robinson et al teaches that this provides for a device which avoids the need for a separate calibration step and provides for the confirmation that various reagents used in the assay procedure are performing according to their specification and to compensate for background interference, temperature and pH changes and other factors originating from the sample matrix which may alter the level of the observed signal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a calibration zone as taught by Wei et al into the device of Good et al because Wei et al teaches that the calibration zones can be useful with essentially any membrane based device and further teaches that the incorporation of calibration zones in lateral flow devices provides for improving sensitivity, and reducing errors that otherwise may be introduced by comparing data produced in one assay with data or reference data produced in a different assay.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a calibration zone as taught by Robinson et al into the device of Good et al because Robinson et al teaches that this provides for a device

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which avoids the need for a separate calibration step and provides for the confirmation that various reagents used in the assay procedure are performing according to their specification and to compensate for background interference, temperature and pH changes and other factors originating from the sample matrix which may alter the level of the observed signal.

With respect to the recitation "retarding the rate of migration of the sample and the non-immobilised molecule" as recited in the instant claims. Since Good et al disclose the same device and disclose the same pore size in the third zone that applicant uses, the device of Good et al would retard the rate of migration of the sample and the non-immobilised molecule. Thus, Good et al reads on the instantly recited claims.

With respect to claims 12 and 13 as instantly recited. Since Good et al disclose the same structure, materials and pore size as instantly claimed. The porous material of Good et al would bind proteins in the range as recited and would also have a capillary flow-rate as recited.

7. Claims 4 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Polzius et al (US 6,130,097) or Schlipfenbacher et al (US 5,160,486).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach the third zone and fourth zone overlapping and the fourth zone and fifth zone overlapping.

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Polzius et al teach that it is known in the art to overlap zones on a test strip to provide for fluid contact of the zones (col 4).

Schlipfenbacher et al teach that it is known in the art to overlap zone on a test strip. Schlipfenbacher et al teach that this provides for the zone to be in liquid contact with one another so that they form a liquid transport path along which a liquid flows, driven by capillary forces, from a start zone (col 1 – col 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate overlapping as taught by Polzius et al and Schlipfenbacher et al into the third, fourth and fifth zones of Good et al because both Polzius et al and Schlipfenbacher et al show that it is known in the art to overlap zones on a test strip and also show that this provides for fluid contact and a liquid transport path. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating overlapping as taught by Polzius et al and Schlipfenbacher et al into the device of Good et al. Further, it is unclear what applicant intends by claim 6 (see 112 second rejection above). Therefore, the combinations above read on the instantly recited claims.

8. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Davis et al (US 6,352,862).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach a second labeled molecule in the second zone and its binding partner in the forth zone.

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Davis et al teach the method and device for determining analytes. Davis et al teach the use of immobilized analytes or analogues and labeled reagents in the strip (col 4, line 64 – col 5, line 3). Davis et al teach the use of several labeled specific binding reagents each carrying a different label in a test strip. Davis et al disclose that this facilitates the manufacture of a multiple analyte testing device (col 4, lines 8-14). Davis et al teaches the use of multiple capture reagents col 8, line 65 – col 9, line 27). Davis et al teach that the determination of more than one analyte can have significant clinical utility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate multiple labeled and multiple immobilized reagents as taught by Davis et al into the modified device of Good et al because Davis et al shows that this facilitates the manufacture of a multiple analyte testing device and also teaches that the determination of more than one analyte can have significant clinical utility. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating multiple reagents as taught by Davis et al into the device of Good et al.

9. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Lee et al (WO 02/04671).

See above for the teachings of Good et al, Wei et al, and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach a spacer molecule or the spacer molecule is bovine serum albumin (BSA).

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Lee et al disclose BSA used as a spacer molecule to immobilize a capture probe to a test strip. Lee et al disclose that the use of this spacer increases the stability of the interaction between the capture probe and the target and thus improves sensitivity of the detection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a spacer molecule such as taught by Lee et al into the modified device of Good et al because Lee et al shows that use of this spacer increases the stability of the interaction between the capture probe and the target and thus improves sensitivity of the detection.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al in view of Lee et al and further in view of Henderson et al (US 2004/0072248).

See above for the teachings of Good et al., Wei et al and Lee et al.

Good et al, Wei et al and Lee et al differ from the instant invention in failing to teach the spacer molecule and the analyte being immobilized to the fourth zone are coupled using CMO.

Henderson et al teach the use of carboxymethyloxime (CMO) conjugated to bovine serum albumin and conjugated to an oestrogen and used as a binding substance. Henderson et al disclose that this binding substance is immobilized on the surface of a test strip and used in assays.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate CMO as taught by Henderson et al into the modified

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device of Good et al because Henderson shows that it is known in the art to use CMO for immobilization of proteins on the surface of test strips. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating CMO as taught by Henderson et al into the modified device of Good et al.

11. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Frushour et al (US 2003/0059951).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach changing the length of the porous material used.

Frushour et al teach that the spatial separation between zones on a test strip and the flow rate characteristics of the porous solid phase material can be selected to allow adequate reaction times during which the necessary specific binding can occur, and to allow the labeled antibody in the labeled antibody zone to dissolve through the porous solid phase material (para. 0055). Therefore, Frushour et al is teaching optimizing the test strip to allow for the desired incubation time.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to change the length of the third zone of Good et al as taught by Frushour et al because Frushour et al teaches that this provides for the optimal reaction times during which the necessary specific binding can occur, and to allow the labeled antibody in the labeled antibody zone to dissolve or disperse in the liquid sample and migrate through the porous solid phase material. Further, the optimal length of the third zone relative to the other zones can be

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determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

12. Claims 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Sundrehagen (US 6,716,641).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to specifically state that the ancillary compound decreases non specific binding and provides release of the non-immobilized molecule.

Sundrehagen discloses the use of reagents in zones on a test strip.

Sundrehagen disclose that the use of these reagents prevents non-specific binding of the detector reagent and/or analyte (col 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate reagents such as taught by Sundrehagen into the modified device of Good et al because Sundrehagen teaches that this provides for the

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prevention of non-specific binding of the detector reagent and/or analyte. Further, it is noted that a review of applicant's specification on pages 25-26 discloses the use of ancillary compounds and what the ancillary compounds provide, but the specification does not disclose a species of the ancillary compound nor provides guidance of what the ancillary compound may be. Therefore, the combination of references teach ancillary compounds the same as applicant has discloses and therefore would be capable of providing the specific characteristics as recited and thus the combination of references read on the claims.

Response to Arguments

13. Applicant's arguments filed 09/11/06 have been fully considered but they are not persuasive.

Applicant argues that Good merely states that the material used in the test zone is a microporous, nitrocellulose material having a pore size of about 0.2 to about 0.5 microns in diameter. Applicant states that there is not suggestion that this material is capable of retarding the rate of migration of the sample and the non-immobilized molecule and that Applicants' porous material has a pore size in the range of 10-50 microns or greater, at least two orders of magnitude greater than that of Good. Applicant directs Examiners attention to page 8, lines 22-30. This is not found persuasive because 1) the features upon which applicant relies (i.e., pore size in the range of 10-50) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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2) Page 8, lines 32-35 of the specification also disclose other pore sizes and 3) the only recitation of the pore size is found in claim 11 which recites wherein the average pore size of the material 10-10,000 nm and the pore size taught by Good 0.2 microns (200 nm) and 0.5 microns (500 nm) clearly fails within this range. Therefore, since applicant has not recited anything structurally different from that of the prior art. The prior art is capable of retarding the rate of migration.

Applicant's remaining arguments directed toward Good as not teaching a calibration zone have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. No claims are allowed.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mendel-Hartvig et al (US 6,916,666) teaches calibration zones used in test strips and teaches the advantages of using calibration zone. Mendel-Hartvig et al teaches the detection zone is located downstream of the calibration zones.

Kuo et al (US 6,183,972) teaches test strips and the use of calibration reagents on the test strip (Figure 1 and Figure 8).

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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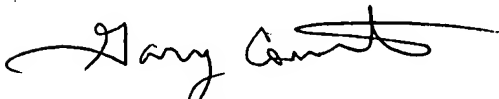
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Gary Counts
Examiner
Art Unit 1641
February 6, 2007



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